PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/HU 03/00090	International filing date *(day/month/year)* 30.10.2003	Priority date *(day/month/year)* 31.10.2002
International Patent Classification (IPC) or both national classification and IPC A61L24/00		
Applicant HUDAK, Istvan		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26.05.2004	01.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Menidjel, R Telephone No. +31 70 340-3680

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/HU 03/00090

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-31 received on 30.11.2004 with letter of 24.11.2004

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 23-31

   because:

   ☒ the said international application, or the said claims Nos. 23-31 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	5-7,25-27
	No:	Claims	1-4,8-24,28-31
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-31
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- The subject-matter of claims 23-31 is related to a method for treatment of the human or animal body from surgery or therapy. Using its discretion, the present authority decided not to carry out an internal preliminary examination on that subject-matter (Article 34(4)(a) PCT in conjunction with Rule 67.1(iv) PCT).

For the assessment of the present claims 23-31 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 - The following documents (D1,D2,D3) are referred to in this communication (Article 33(6) PCT); the numbering will be adhered to in the rest of the procedure:

D1: US-B-6 296 6041 (GARIBALDI JEFFREY M ET AL) 2 October 2001 (2001-10-02)
D2: EP-A-0 280 451 (PFIZER) 31 August 1988 (1988-08-31)
D3: US 2001/004710 A1 (RYDELL MARK A ET AL) 21 June 2001 (2001-06-21)

2. Article 34(2)(b) PCT

- The amendments filed by the applicant with the letter dated 24.11.2004 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT:

The amended claims disclaim more than the strict disclosure of the prior art document D1, which was a novelty destroying document. Document D1 referred to a polyurethane based composition for filling or short-circuiting vascular cavities and its uses. The biocompatible polyurethane used in document D1 combines a precipitating polymer such as polyurethane, an adhesive to provide adhesion and cohesion to the vessel such as glue, and a magnetic embolic agent which allows the magnetic embolic agent to be controlled by a magnetic field applied by an external source magnet.

- Therefore, the following discussion concerning novelty, inventive step and industrial applicability will be based on the claims as filed:

3. Novelty (Article 33(2) PCT)

- The subject-matter of present claims 1-4,8-24,28-31 is not new for the following reasons (Article 33(2) PCT):

- Document D1 (US6296604), cited by the Applicant, refers to a polyurethane based composition for filling or short-circuiting vascular cavities. The biocompatible polyurethane used in document D1 combines a precipitating polymer such as **polyurethane, an adhesive to provide adhesion and cohesion to the vessel such as glue**, and a magnetic embolic agent which allows the magnetic embolic agent to be controlled by a magnetic field applied by an external source magnet. The polyurethane polymer is dissolved in a biocompatible solvent chosen from the group comprising dimethylsulfoxylate, ethyl alcohol, ethyl acetate and preferably acetone (Cf. D1, column 2, line 63-column 3, line 7; column 3, lines 53-62; column 4, lines 13-23; claims 1-9).
The subject-matter described in document D1 takes away novelty of present claims 1-4,8-15,19-24,28-31.

- Document D3 (US2001/004710) describes a curable polyurethane composition for repairing a tissue site. Document D3 refers also to a kit that can be used to prepare the polyurethane based composition (Cf. D3, page 1, paragraph 1-paragraph 3; page 4, paragraph 42-paragraph 51; page 4, paragraph 60-page 5, paragraph 63; page 5, paragraph 66-paragraph 68).
The subject-matter of document D3 takes away novelty of present claims 12,13,16-22.

3. Inventive Step (Article 33(1),(3) PCT)

a - Since the subject-matter of present claims 1-4,8-24,28-31 is known, obviously it can not involve an inventive step (Article 33(1),(3) PCT).

b - The remaining subject-matter, which is the subject-matter of present claims 5-7,25-27 does not involve an inventive step for the following reasons (Article 33(1),(3) PCT):

- The subjective problem to be solved by the present application is to provide a polyurethane based composition showing excellent features and applicability for occluding or short-circuiting vascular cavities.

- The solution proposed in the present application is the use of polyurethane in the manufacturing of composition or kit for filling or short-circuiting vascular cavities, where the

polyurethane used can be dissolved in a solvent or a solvent mixture mingling with body fluids (see claim 1 as filed).

- Document D1, cited by the Applicant, which is considered as the closest prior art, refers to a polyurethane based composition for filling or short-circuiting vascular cavities. The biocompatible polyurethane used in document D1 combines a precipitating polymer, i.e. polyurethane, a glue and a magnetic embolic agent. The polyurethane polymer is dissolved in a biocompatible solvent chosen from the group comprising dimethylsulfoxylate, ethyl alcohol, ethyl acetate and preferably acetone (Cf. D1, column 2, line 63-column 3, line 7; column 3, lines 53-62; column 4, lines 13-23; claims 1-9).

- The difference between the teaching of the closest prior art and the claimed subject-matter appears to be the main diol component of the polyurethane used and the main diisocyanate component of the polyurethane.

- Document D2 (EP0280451) describes purified diisocyanate polyurethane prepolymers, process thereof, and a method of using same as space filling adhesive sealant in surgery. The diisocyanate used in the preparation of said biocompatible polyurethane corresponds to diphenyl-methane-4,4'-diisocyanate (MDI) (Cf. D2, page 2, lines 3-30; page 3, lines 14-52; page 4, lines 6-58; page 6, lines 11-34).

- The feature of present claims 5-7,25-27 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.
Therefore, the subject-matter of present claims 5-7,25-27 does not involve an inventive step (Article 33(1),(3) PCT).

Claims 23-31 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

4. Industrial Application (Article 33(4) PCT)

- The subject-matter of present claims 1-22 is considered to be industrially applicable; claims 1-22 therefore, satisfy the criterion set forth in Article 33(4) PCT.